**REMARKS**

Claim 10 has been canceled. A new claim, claim 23, has been added to the application. New claim 23 positively recites that the solid preparation for dialysis defined therein does not contain sodium bicarbonate.

Reconsideration of the rejections in the Action dated October 29, 2003, is requested.

The 35 U.S.C. § 112, second paragraph, rejection is moot in view of the cancellation of claim 10.

Claims 1, 4, 7-11 and 13-22 are rejected under 35 U.S.C. §102(b) as being anticipated by EP 0399918 ("EP '918"). Reconsideration and removal of the 35 U.S.C. § 102 rejection is respectfully requested.

The present invention is directed to a solid preparation for dialysis comprising a mixture of (1) a first composition comprising core particles comprising particles of sodium chloride, and a coating layer covering the core particles and containing (a) 0 to 50% by weight of sodium chloride and (b) 100 to 50% by weight of one or more electrolyte selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate, the first composition being granulated into granules having an average particle diameter of 300 to 1,700μm, (2) a second

composition comprising core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or a different sugar, the second composition being granulated into granules having an average particle diameter of 300 to 1,700μm, and (3) an acid.

The solid preparation in the present invention corresponds to the first composition in EP '918 and does not contain sodium bicarbonate. The solid preparation of the present invention is mixed with sodium bicarbonate (see, page 14, line 15, to page 15, line 3) to prepare a dialyzate containing sodium bicarbonate (i.e., a blood dialyzate) (see, the composition, page 15, lines 5-18). Therefore, the solid preparation for dialysis of the present invention comprising (1), (2) and (3) is different from the two compositions in EP '918 in which the second composition contains sodium bicarbonate. The solid preparation of the present invention must be compared with the first composition of EP '918.

Regarding the first composition of EP '918, the Office indicates in the Action that "the first composition contains 2188.7 parts sodium chloride particles with a coating layer of 35.6 part magnesium chloride hexahydrate, 77.2 parts calcium monohydrate [sic] monhydrate, 215.2 parts of sodium acetate trihydrate, and acetic acid with instant sizes (Examples 1-3)." However, in the

first composition of Example 1 of EP '918 sodium chloride is neither a core particle nor is it coated with a layer of other electrolytes because 2188.7 part of sodium chloride, 52.2 parts of potassium chloride, 77.2 parts of calcium chloride, 35.6 parts of magnesium chloride and 215.2 parts of sodium acetate are mixed by stirring, pulverizing and pelletizing in Example 1 and then mixed with acetic acid. Particles of sodium chloride are not coated in Example 1.

The Office also argues that in EP '918, the "examples and claims show that glucose particles are added to the electrolyte composition (page 4 and 8-9)". However, by the dry method disclosed in EP '918, the first composition is obtained by stirring and mixing the solid electrolytes for dialysis and glucose with a stirring and mixing device (page 8, lines 5-11). The glucose is not a core particle and is not a particle coated with a coating layer comprising glucose or a different sugar although the first composition include glucose.

Moreover, the Office has not shown that the glucose particles of EP '918, per se, have a particle diameter of at least 300μm. The position of the Office is that glucose coated with glucose is still glucose. However, the particle diameter of glucose which is commercially available has a particle diameter of 300μm or less

(see, for example, Example 1 in the present application in which the glucose particles have a diameter of 180μm). Because the first composition (electrolytes) of the solid preparation of the present invention has an average particle diameter of 300 to 1,700μm, the second composition (sugars) should have an average particle diameter of 300 to 1,700μm to be mixed homogeneously with the first composition in a mixer such as a V-type mixer. And since both the first composition and the second composition have similar particle diameters, they are miscible to make a homogeneous mixture which can dissolve quickly into water and show content homogeneity (see, page 11, line 21, to page 12, line 4, of the present application).

On the other hand, if glucose particles are simply added to the electrolyte composition (pages 4 and 8-9, in EP '918), the solid preparation for dialysis by a dry granulation method (as shown in Comparative Example 2 in the present application) will have a non-homogenous content of glucose (see, page 21, Table 1).

The Examiner has noted that in Example 2 in EP '918, sodium chloride is sprayed with an aqueous solution of the instant electrolytes. However, glucose is not included in the electrolytes and thus is not part of the first composition.

As mentioned above, the cited reference, EP '918 neither describes nor suggests that the sugar particles (second composition

in the present invention) have a similar particle diameter to that of the electrolytes (first composition in the present invention) to allow the compositions to be homogeneously mixed together. In particular, it is not suggested to separate the glucose from the electrolytes such as sodium chloride, calcium chloride, magnesium chloride, potassium chloride and sodium acetate, or sodium bicarbonate to prevent decomposition and coloring.

Moreover, applicants note that claims 8 and 9, written in product-by-process terminology, (and the claims dependent thereon) exclude sodium bicarbonate from the solid preparation for dialysis of the present invention. Claims 8 and 9 recite the solid preparation for dialysis "as being prepared by a process comprising" certain specific steps. The term "comprising", when used in a claim to recite method steps, leaves the claim open to other steps, but does not affect the scope of the components recited within the steps. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 [229 USPQ 805] (Fed. Cir. 1986) in which the Federal Circuit rejected as "far too broad" the argument that "comprising" opened the claims to additional steps and additional limitations not contained in the accused method. Since sodium bicarbonate is not a component of the materials used in the recited steps, it is excluded from the scope of claims 8 and 9.

Claims 8 and 9 recite the step of "spraying, onto core particles comprising particles of a sugar, an aqueous solution of said sugar or a different sugar to obtain second coated particles, and drying the second coated particles to obtain granules of a second composition having an average particle diameter of 300 to 1,700 μm". The term "comprising" recited in the step may leave the step open to core particles other than particles of a sugar, but does not leave the claim open to particles other than the core particles. Additionally, the step requires that the core particles be coated with a sugar.

For the above reasons, EP '918 also cannot anticipate the solid preparation recited in claims 8 and 9 and the claims dependent thereon.

Removal of the 35 U.S.C. § 102 rejection and a notice of allowability of the present application are believed to be in order and are respectfully solicited.

A check in the amount of $86.00 for the fee for an excess independent claim (claim 23) is submitted with this sibmission.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any other fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK

Ronald J. Kubovcik
Reg. No. 25,401

Atty. Case No. NPR-085
The Farragut Building
Suite 710
900 17th Street, N.W.
Washington, D.C. 20006
Tel: (202) 887-9023
Fax: (202) 887-9093
RJK/cfm